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July 28, 2020

VIA CM/ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court for the District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Joel Schneider, U.S.M.J.
U.S. District Court for the District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*,
No. 1:19-md-02875-RBK-JS (D.N.J.)

Dear Judge Kugler and Judge Schneider:

Plaintiffs respectfully submit this letter brief in advance of the upcoming July 29, 2020 telephonic case management conference.

I. Plaintiff Fact Sheets

Following a productive meet and confer call early this week, it is Plaintiffs' understanding that the only remaining issues relate to cases where no PFS has been served at all.

II. Defendant Fact Sheets

As the Court is aware, the parties began negotiations over the DFSs in January of this year. Over the course of these negotiations, a tiered approach to the completion of the DFS was devised, whereby each defendant sued by a particular plaintiff completes a DFS based upon that defendant's

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place in the drug supply chain. The parties agreed on three separate DFSs to be completed in the following order: (1) Retailers, followed 60 days later by, (2) Wholesalers/Distributors/Repackagers, followed 60 days later by, (3) API/Finished Dose Manufacturers. In this way, each level of defendant can use the information provided by defendants lower in the supply chain to inform their responses to the DFS.

The dispute central to each DFS concerns the “triggering event.” In other words, what event constitutes the trigger for the Retailers to begin the process of completing a DFS, and thereby setting the entire DFS process in motion? Plaintiffs have proposed the following language:

Further, no (insert defendant level) Defendant will be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS. A PFS shall be deemed “substantially complete” if all of the applicable information requested in section one of the PFS is provided, including but not limited to copies of prescription and/or pharmacy records demonstrating use of a Valsartan-containing drug, and for personal injury Plaintiffs, including a signed HIPAA authorization form and medical records and/or a certification under oath demonstrating that he or she has been diagnosed with the injury claimed in the PFS.

This language tracks the requirements of Section I of the PFS: “Core Case Information.” Defendants agree that the DFS time period should begin when the PFS is “substantially complete” prior to the triggering of the DFS, but do not want to define what that term actually means. For example, a defendant may deem a PFS not substantially complete for failure to list the details of a plaintiff’s bankruptcy which occurred 25 years ago, while another may deem a PFS not substantially complete for failure to list a previous employer’s address.

Plaintiffs’ proposal provides clear direction and will avoid pointless disputes. The only information the Retailer defendants actually need to begin their DFS (and to set the entire DFS process in motion) is a plaintiff’s name, date of birth, and social security number. As such,

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Plaintiffs are concerned that Defendants will delay the triggering of their DFS obligation by making their own unilateral determination that a PFS is not “substantially complete.” The Court will recall that Retailer defendants are not required to submit their DFS until 60 days after the completion of the PFS, and if each defendant in the supply chain takes the allotted 60 days to complete the DFS, the process once triggered will take *half a year* to complete. Thus, if the Defendants are allowed to make their own determination as to what constitutes a substantially complete DFS, there is no certainty as to when this process will begin, and how long it could take.

There are other minor disputes that remain with respect to the Retailer, and Wholesaler/Distributor/Repackager DFSs and the parties will be prepared to discuss these with the Court.

III. Short Form Complaints

Plaintiffs and Defendants have been conferring on an ongoing basis to resolve new short-form complaint issues as they arise. At this point, Plaintiffs do not believe any issues require the Court’s attention at this time.

IV. Coordination of State Court Cases

Approximately 14 cases are now pending in New Jersey Superior Court. Plaintiffs believe this is an inadequate number to request assignment of an MCL. It is Plaintiffs’ understanding that the current filed cases are stayed or will be stayed.

V. Schedule for General Causation

Defendants have made no secret of their desire to litigate the personal injury cases prior to the economic loss class action claims. This request by the Defendants is yet another effort to push the personal injury claims ahead of or into the economic loss phase that the Court has directed.

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Defendants seize on but mischaracterize the Court's observation that we will be transitioning to another phase of the case, which is debatable in light of multiple Defendants' request for a re-do on the search term methodology, and was a commentary on the transition from framing the discovery requests to starting the production of the discovery. The current proposal is to insert the personal injury general causation issues before any of the economic class issues are engaged or decided, a proposition which we believe the Court has soundly rejected in favor of advancing the class claims toward a motion for certification under Rule 23 and a trial or trials of those claims thereafter. Doing so will disrupt the massive amount of work that is already underway, focused on the document productions, the motions to dismiss, to be followed by class representative and corporate fact witness discovery, then the expert phase for the economic loss claims. Accordingly, it is premature to address the timing to address general causation in the personal injury context. Plaintiffs continue to support establishment of a timetable for deposition of the economic loss class representatives, depositions of corporate fact witnesses, the related expert disclosures/depositions/Daubert motions, motion for class certification, and an economic class trial or trials.

VI. Teva's Motion Regarding Technology Assisted Review

The parties have submitted briefs on this issue, which flows from Teva's request to scrap roughly a year of work and hundreds of hours of work, including a massive commitment of time and effort from the Court to establish the search terms methodology, in order to substitute a new AI methodology that remains undefined at present. The level of distraction this has already injected is substantial, and the prejudice to Plaintiffs will only accumulate. Moreover, every case cited by the defense strongly supports Plaintiffs' position that it is too late – for example, the 2013

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Biomet case they now rely on addressed a protocol negotiated at the outset of an MDL where the defense had already been producing documents around the country before formation of the MDL, the defendant agreed to add more search terms, the plaintiffs had input to the protocol, and most important **the defendant agreed to produce all of the non-privileged “non-responsive” documents to the plaintiffs.**

The time to negotiate a complex search terms/TAR hybrid protocol was last year, when the parties had the time and bandwidth to do so, not in the midst of the document production. The idea that Plaintiffs should now endure this level of distraction, potentially with regard to three defendants, is completely inequitable. Teva’s request for sanctions under these circumstances is completely tone deaf. Defendants had every opportunity to fully test their proposed search terms protocol, and address all the issues they would have found, but they chose not to. As Judge Cavanaugh observed in *Mercedes-Benz*, the producing party can choose to use search terms, but cannot later come back and complain and seek to un-do that decision based on arguments of burden. That observation, in a case touted by the defense, should be dispositive here. And if Teva is permitted to proceed with TAR, it must be with transparency and material input from Plaintiffs, with Plaintiffs’ prioritization requests fulfilled, and all non-privileged documents produced.

Respectfully,



ADAM M. SLATER

cc: All Counsel (via CM/ECF)